



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Docket No. 400140)

In re the Application of:

DONALD K. JONES et al.

Serial No.: 09/880,506

Filed: June 13, 2001

For: OCCLUDING VASCULATURE OF A  
PATIENT USING EMBOLIC COIL WITH  
IMPROVED PLATELET ADHESION

To: Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Art Unit: 3743

Examiner Kathryn Odland

RECEIVED

MAY 26 2004

TECHNOLOGY CENTER R3700

**DECLARATION UNDER 37 C.F.R. SECTION 1.131**

I, Donald K. Jones, declare as follows:

1. I am a co-inventor of the invention disclosed and claimed in the above identified application.

2. I have a degree in material science and engineering. I have worked in the field of biomedical engineering, including embolization devices, for over seven years. I am an inventor in numerous patents relating to neurological devices.

3. It is my understand that U.S. Patent No. 6,280,457 to Wallace et al., filed June 4, 1999, has been cited by the Patent and Trademark Office in support of rejections of claims 1-4, 6-14, 16, 17, 20, and 27 of the above-identified application.

4. The invention of this application was made prior to June 4, 1999, the date of filing of U.S. Patent No. 6, 280,457. More specifically, the invention was made and completed, and actually reduced to practice, all in the United States of America, prior to June 4, 1999, as evidenced by the attached exhibits.

5. Exhibit A is a date-redacted copy of an invention record disclosure signed by Vladimir Mitelberg and me. Exhibit A reports on work performed by us and/or under our direction and control in the United States of America prior to June 4, 1999, in connection with making embolic coils for occluding the vasculature of a patient, which devices were made and reduced to practice before June 4, 1999.

6. With respect to Exhibit A (the invention record) referred to in paragraph 5 above, the photographs set forth in the last page of this invention record were taken by me of the roughened coils prior to submitting them for evaluation. The page having the number 028122 shows service requests. The picture on the bottom is a service request in which the coils were submitted for evaluation. Four photomicrographs were taken as indicated by the middle box and these four microphotographs were the results of the service requests. These photomicrographs are on the page of Exhibit A following the service requests. All of these photographs and service requests were taken and made prior to June 4, 1999.

7. Exhibit B are date-redacted copies of experiments performed on baboons, in connection with occluding the vasculature of the baboons, which experiments were performed before June 4, 1999.

8. The work referred in paragraph 7 above, included ex-vivo tests outside of the body using the baboon. A silicone tube was connected to the artery of the baboon. Blood flow was through the silicone tube and back to the baboon. In the silicone tube, aneurysms were formed on the tube itself. A delivery catheter was used to place roughened embolic coils inside of the aneurysms, with the help of a pusher mechanism. Live blood was run through the system and radioactive platelets accumulated on the

coils. The coils used were textured 5 mm. complex coils. By using a gamma camera imager, the radioactivity was measured. Non-textured coils were also used. It was found that there were greater amount of platelets on the roughened coils then on the non-roughened coils. From these experiments we were able to conclude that the introduction of the textured coils in the aneurysm would enhance platelet adhesion.

9. In view of my experience in biomedical engineering (including embolization devices) prior to June 4, 1999, I was confident that the vasculature of a patient could be successfully occluded by providing a plurality of embolic coils having a proximal portion that is held by the detachment portion and a distal portion, with the proximal portion that is held by the detachment portion being relatively smooth and the distal portion having a relatively textured surface. I found that the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting. As a result of the experiments, I was confident that the embolization device having a roughened surface was suitable for placement in a catheter for being conventionally implanted with an introducer having a detachment portion to provide improved platelet adhesion compared to a non-textured surface, to promote clotting. Accordingly, in my view, the invention was reduced to practice on a date prior to June 4, 1999, because I was confident that clinical versions of the prototype could be sterilized and clinically used with success to embolize aneurysms in patients.

10. I hereby declare that all statements made herein and of my own knowledge are true, and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issued therefrom.

Date: 5/11/04

  
\_\_\_\_\_  
Donald K. Jones

PATENT

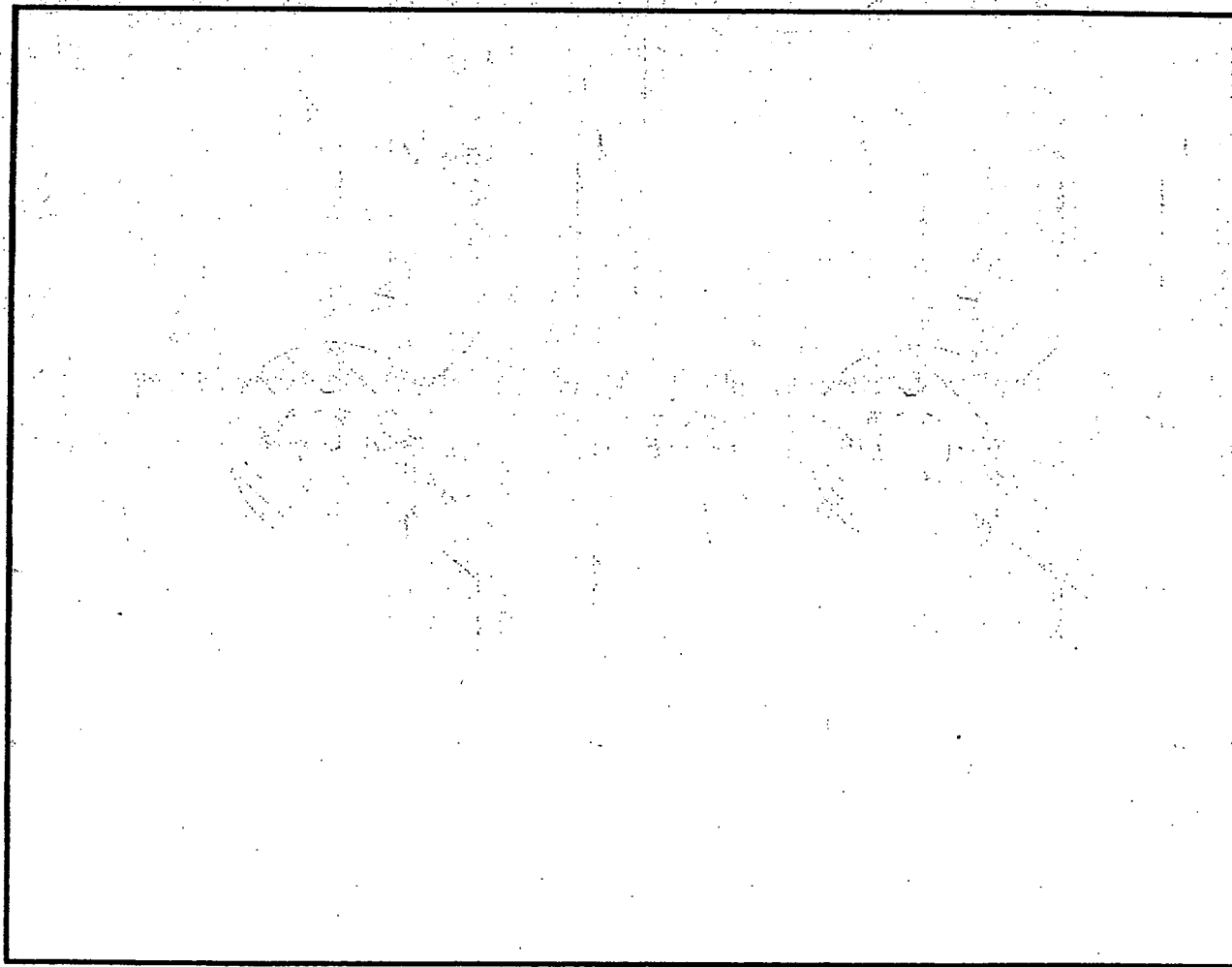
**Cordis**

DEPARTMENT

00/140

**DESCRIPTIVE TITLE: Coil Surface Modification**

- I. **INSTRUCTIONS:** This form should be typed, except for the signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required. Each original piece of paper must be signed and dated by every inventor and by each witness.
- II. **ILLUSTRATION:** *Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention.*



Name & Signature of Inventor(s):

Date

Witnesses

Date

V. H. S.  
Donald R. Jones

E. A. S.  
W. H. S.

**EXHIBIT A**

**III. EXPLANATION OF INVENTION:** *Describe the invention completely, including all essential elements.*

The invention is a surface modified embolization coil. The surface has been texture by abrasion or "sand blasting". Fifty-micron diameter alumina particles were used to texture the surface of the platinum tungsten wire used to form the coils. It is believed that the textured surface provides improved platelet adhesion thus promoting clotting and subsequent endothelialization. SEM micrographs and optical pictures of the textured vs. non-textured are attached. Testing using radiolabeled platelets was conducted to evaluate an ex vivo aneurysm model. In the model, aneurysms treated with textured coils were compared to aneurysms treated with non-textured coils. The textured coils showed an increase in the platelet deposition of about 50% over the non-textured coils.

**IV. NOVEL FEATURES AND ADVANTAGES:** *What is new that was not previously known, and why is this important.*

Other surface modification techniques such as coating or ion implantation require expensive and elaborate equipment to modify the coils which add an additional component. This method does not impart any new materials to the coil that would require new biocompatibility testing and can be done inexpensively.

**V. MODIFICATIONS:** *Describe all possible modifications or alternate embodiments.***VI. RELATED DOCUMENTS:** *List all known relevant art references (patents, publications, commercially available products, etc.). Please supply copies of the documents, if available.*

Patents:

Publications:

Signature of Inventor(s):

Date:

Witnesses:

Date:

V. Mueg

Donald E. Green

E. Mueg  
Donald E. Green

VII. INVENTORS:

DEPARTMENT

First Inventor's Full name (Please type:)

Donald K. Jones

Signature: Donald K. Jones

Date:           

Second Inventor's Full Name (Please type:)

Vladimir Mittelberg

Signature: V. Mittelberg

Date:           

VIII. WITNESSES: This invention was disclosed to and understood by:

Full Name of First Witness (Please type: Eric Cheng)

Signature: Eric Cheng

Date:           

Full Name of Second Witness (Please type:)

Boles Shkolnick

Signature: Boles Shkolnick

Date:           

IX. ADDITIONAL INFORMATION:

Invention is recorded on page(s):            of Notebook No.:            dated:           

Earliest date:            and place: CES where inventors first  
thought of the present invention.

First written description (date and present location):           

First sketch of the invention (date and present location):           

Earliest date:            and place:            where first operating  
model  
was completed.

Present location of model:           

Earliest date of use of the invention (actual or contemplated):           

Earliest shipping date (actual or contemplated):

## Service Request

Job number, assigned by  
supplying organization

32 02 7

R q u e s t	To	CPQA, EML LAB		
	From (organization)	CES		
	Location	PETER GUINONES x 81020		
	For information contact	81020		
	Description of request	PLEASE PROVIDE SEM PHOTOS OF SURFACE OF COILS PROVIDED FOR ROUGHNESS EVALUATION.		
	Requested by	P. Guinones		
Approved by				
	Date			
	Date			

S u p p l i e r	Date received				
	Labor cost				
	Material cost				
	Purchased Materials, services or equipment required	Workbook 92071-46			
	Completion date				
	Comments	Electron optical micrographs were taken of each sample at low & high magnifications to show surface roughness conditions.			
	Estimate by	John Dault		Date	1/1

A p p r o v a l	Cost and completion date accepted by requestor			
	Signature			
	Date			
	Comment			
	Supplier acceptance by	[Signature]		Date

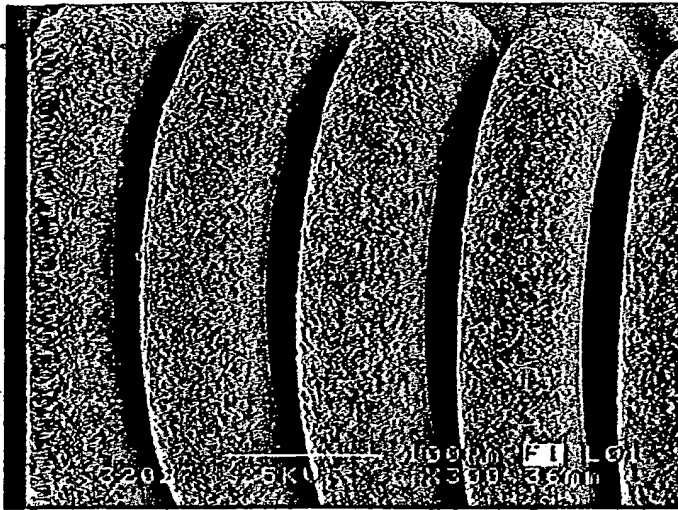


Figure 1-(233x) Sample with rough surface

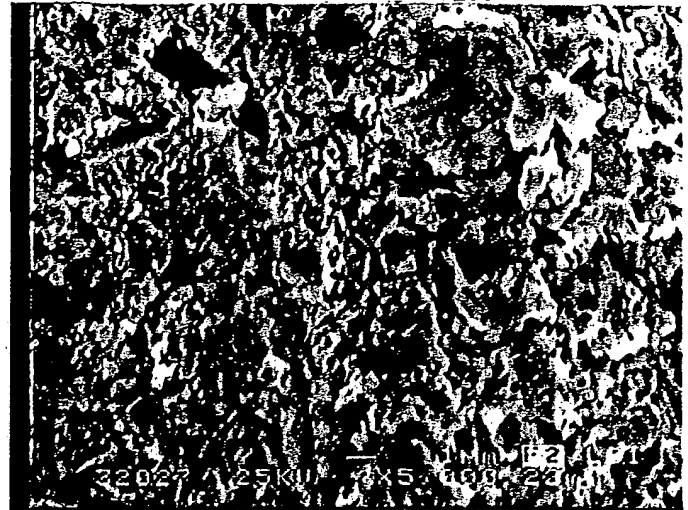


Figure 2-(3880x) Sample with rough surface

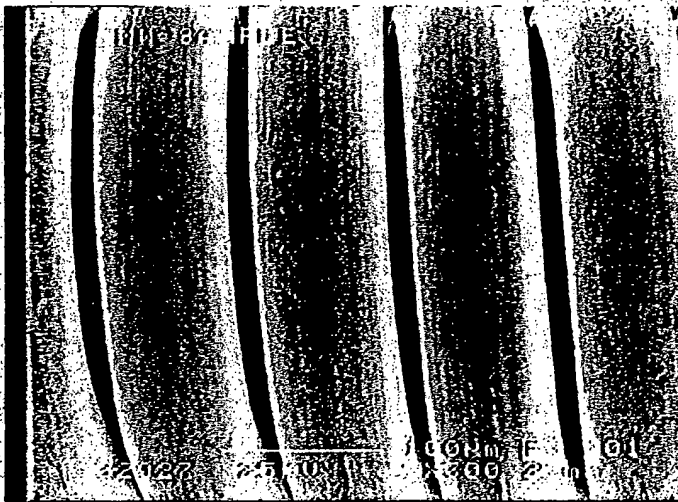


Figure 3-(233x) Sample "MW" with smooth surface.

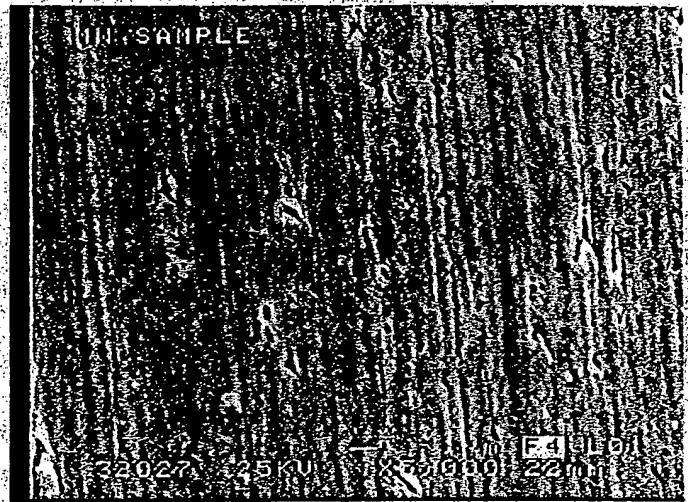


Figure 4-(3880x) Sample "MW" with smooth surface.

*David K. Price*

40 X Mag

.003" H<sub>2</sub>O

5mm  
Complex  
(120-mg)

No Surface Treatment



PAT

DEPAR

DXF

40 X Mag

.003" H<sub>2</sub>O

5mm  
Complex  
(120-mg)

Surface Treatment



200000 X Mag

Surface Abraded using AumBRADe - 5 31413  
50 micron blend of Al<sub>2</sub>O<sub>3</sub> (Patin LP105)

DXF

**Computer  
Data Partition**

## Study Description

**Aneurysm Run #7 textured 5mm dim. complex coils. Tail from Aneu. #1 extended 130mm. Tail from Aneu.#2 extended 180mm**

## Iodine

Remarks

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#1

Time

Min

5

10

153

20

**25**

30

35

40

45:00

50

55

60

85

70

00  
75

30  
08

00

50

100

105

110

115

120

**125.**

130

135

140

145

150

3

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**Yerkes Research Center**

Page 1

**EXHIBIT B**

Baboon B384right  
Date

Computer  
Data Partition  
Camera

Study Description

Aneurysm Run #7 textured 5mm dim. complex  
coils. Tail from Aneu. #1 extended 130mm.  
Tail from Aneu. #2 extended 180mm

ROI (device)

Window  
Energy

> 172

> 247

low

med

word

byte

Collimator

>

Matrix

128

>

Iodine

Remarks

#2 ROI ROI

Time CPM

Min	CPM	CPM bkg	Thrombus	Standard	Pits x10 <sup>3</sup>
6	216	169	47.00	0.000511	0.02
10	255	224.00	31.00	0.000511	0.02
15	267	255.00	12.00	0.000511	0.01
20	428	341.00	87.00	0.000511	0.04
25	551	431.00	120.00	0.000511	0.06
30	665	583.00	82.00	0.000511	0.04
35	902	798.00	104.00	0.000511	0.05
40	1020	792.00	228.00	0.000511	0.12
45	1170	892.00	87.00	0.000511	0.04
50	1260	929.00	331.00	0.000511	0.17
55	1300	947.00	353.00	0.000511	0.18
60	1330	964.00	366.00	0.000511	0.19
65	1360	998.00	362.00	0.000511	0.18
70	1440	998.00	442.00	0.000511	0.23
75	1510	985.00	525.00	0.000511	0.27
80	1540	1020.00	520.00	0.000511	0.27
85	1740	1100.00	640.00	0.000511	0.33
90	1620	1040.00	580.00	0.000511	0.30
95	1540	1000.00	540.00	0.000511	0.28
100	1490	1050.00	440.00	0.000511	0.22
105	1800	988.00	612.00	0.000511	0.31
110	1600	892.00	708.00	0.000511	0.36
115	1600	956.00	644.00	0.000511	0.33
120	1680	903.00	777.00	0.000511	0.40
125	1850	954.00	696.00	0.000511	0.36
130	1680	892.00	788.00	0.000511	0.40
135	1680	860	820.00	0.000511	0.42
140	1770	806	984.00	0.000511	0.49
145	1740	790	950.00	0.000511	0.49
150	1700	844	856.00	0.000511	0.44

Pit Cnt Pre 314  
Pit Cnt Post 267  
WBC 8.7  
Hct Pre 41.10%  
Hct Post 38.00%  
Flow (ml/min) 100 clamp

Whole Blood 171188  
Plasma 21908  
Fraction 92.5%  
Free 7.5%  
Volume (cc) 3

Blood Std CPM 2285  
Bkg CPM 291  
Bkgd CPM 1 1994  
CPM in-plts 1843.696  
CPM/ml in-plts 614.5654  
FINIAL 0.000511

ROI ROI

Time CPM

Min	CPM	CPM bkg	Thrombus	Standard	Pits x10 <sup>3</sup>
155	1650	824	826.00	0.000511	0.42
160	1760	858.00	902.00	0.000511	0.48
165	1780	886.00	894.00	0.000511	0.48
170	1800	852.00	948.00	0.000511	0.48
175	1780	788.00	992.00	0.000511	0.51
180	1780	838.00	942.00	0.000511	0.48
185	1880	852.00	1028.00	0.000511	0.53
190	1850	888.00	962.00	0.000511	0.49
195	1850	758.00	1092.00	0.000511	0.56
200	1680	840.00	840.00	0.000511	0.43
205	1680	744.00	936.00	0.000511	0.48
210	1750	788.00	962.00	0.000511	0.49
215	1720	848.00	872.00	0.000511	0.45
220	1610	738.00	872.00	0.000511	0.45
225	1740	794.00	946.00	0.000511	0.48
230	1770	832.00	938.00	0.000511	0.48
235	1700	778.00	922.00	0.000511	0.47
240	1660	780.00	880.00	0.000511	0.45

Baboon 374Plet  
Date

Computer  
Data Partition

Camera

ROI (device)

Window

Energy

Collimator

Matrix

128

Study Description

Aneurysm Run #1 untextured 5mm diam. complex

colls. Tail from Aneu. #1 stopped 1.25" from aneu.

#2. Tail from Aneu.#2 extended 16"

flow stopped at 1hr 25min - shunt was flushed

Remarks

A3

A341

GE

8 x 10

15%

> 172

> 247

> low

> med

> word

> byte

Pit Cnt Pre 295

Pit Cnt Post 204

WBC 11.5

Hct Pre 45.40%

Hct Post 42.10%

Flow (ml/min) 100/clamp

Whole Blood 121465

Plasma 16014

Fraction 92.8%

Free 7.2%

Volume (cc) 3

Time

Min

CPM

CPM.bkg

Thrombus

Standard

Pits x10<sup>9</sup>

ROI

ROI

ROI

ROI

ROI

ROI

ROI

ROI

ROI

ROI

ROI

ROI

ROI

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